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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/677,694

10/02/2003

Nader Najafi

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

NOTIFICATION DATE

DELIVERY MODE

02/09/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/677,694	Applicant(s) NAJAFI ET AL.	
	Examiner PATRICIA C. MALLARI	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-31, 33-40, 44, 48-58, 62, 65 and 67-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31 is/are allowed.
- 6) ☒ Claim(s) 1-14, 17-30, 33-40, 44, 48-58, 62, 65, 67-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicants' amendments to the claims.

Response to Amendment

The amendment filed 6/6/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

New figure 7 shows an embodiment of a closed-loop pacing/ICD tuning system comprising a reader 104, 202, a power unit 107, and a pacing/ICD unit 106, wherein the reader receives data from the implant and transmits it to the pacing/ICD unit, the power unit provides power to the implant, and the pacing/ICD unit interrogates the implant. There is no support in the original specification for such an embodiment. Page 11 of the original specification presents four embodiments of the closed-loop pacing/ICD tuning system:

- 1) the pacing/ICD unit directly interrogates the implant
- 2) the pacing/ICD unit directly interrogates the implant and an external unit transmits power to the implant
- 3) an external reader receives data from the implant and transmits the data to the pacing/ICD unit

4) both the external reader and the pacing/ICD unit interrogate and/or power the sensor.

In none of these disclosed embodiments is there both an external reader and a power unit, as shown in figure 7.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 17-30, 33-40, 44, 48-58, 62, 65, and 67-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a system comprising at least one sensing device, a pacing/ICD unit for interrogating the sensing device, an external unit for powering the sensing device, and a non-implantable readout device for telecommunication and wireless powering of the sensing device. Claim 2 recites a system comprising at least one sensing device, a non-implantable reader allowing telecommunication and wireless

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powering of the sensing device, an external unit operable to transmit power to the sensing device, and a pacing/ICD unit which may interrogate the sensing device. Page 11 of the original specification discusses the system as part of a closed-loop pacing/ICD tuning system. In such a system, several embodiments are described:

- 1) the pacing/ICD unit directly interrogates the implant
- 2) the pacing/ICD unit directly interrogates the implant and an external unit transmits power to the implant
- 3) an external reader receives data from the implant and transmits the data to the pacing/ICD unit
- 4) both the external reader and the pacing/ICD unit interrogate and/or power the sensor.

None of these disclosed embodiments include a description of a system wherein the reader powers the sensing device, the external unit powers the sensing device, and the pacing/ICD unit interrogates the sensing device and the reader transmits data to the reader which then retransmits data to the pacing/ICD unit, as claimed.

Response to Arguments

Applicant's arguments filed 10/9/08 have been fully considered but they are not persuasive. The applicants' set forth several arguments with respect to the rejection under 35 U.S.C. 112, 1st paragraph and the new matter objection:

As to the applicants' particular argument that "the system" must include a sensing device and reader, such an assumption is contrary to the language used in the

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first full paragraph on page 11 of the original specification. In particular, certain lines of that paragraph cite “an intermediate reader unit” and “an external reader”. The usage of the terms “an” to refer to the reader rather than “the” indicates that the reader is not already assumed to be part of the system.

As to the applicants’ comment that the term “additional” in the phrase “additional, external unit” in the first full paragraph on page 11 of the original specification is meaningless if the reader is not included, the examiner disagrees. The term “additional” clearly differentiates the external unit from the pacing/ICD unit in the context of the paragraph and without reference to the external reader.

As to the applicants’ observation that nothing in “paragraph 11” expressly states that the reader is not a component of the system and nothing in the paragraph suggests the reader cannot be a component of the system, the applicants should note that the lack of stating that the reader is *not* a component is not the same a disclosure that the reader *is* a component. Further the applicants believe that the embodiment described in “paragraph 11” describe a pacing/ICD unit and an external power unit as additional components of the claimed system. The examiner disagrees with this assessment. The specification fails to clearly set forth that “the system” is inclusive of the sensing device and reader. In fact, in addition to the reasons cited above, the bottom of page 10 states “In addition to the basic implant-and-reader system, a number of other embodiments of the technology can be realized to achieve additional functionality”, which implies that the following paragraphs are alternative embodiments and not additional features. Further, the disclosure on p. 11 of the specification specifically

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describes the usage of reader in cases in which the reader is used. One cannot reasonably take the lack of mention of a reader to be a disclosure that a reader is included.

The applicants included an unnecessary reminder at the end of their remarks regarding evaluating claims for obviousness. It is noted that an assessment of the prior art with respect to claims rejected under 35 U.S.C. 112, 1st paragraph was indeed included.

Allowable Subject Matter

Claim 31 is allowed. The allowability of claim 31 was addressed in previous Office actions filed 11/2/05 and 8/14/06.

No statement of allowability is being given at this time for claims 1-14, 17-30, 33-40, 44, 48-58, 62, 65, and 67-72 in light of the rejection under 35 U.S.C. 112, 1st paragraph set forth above. Upon resolution of the 112 issues, the prior art will be revisited. However, the prior art of record fails to teach or fairly suggest a system having a sensing device, a non-implantable readout device or reader, external unit, and pacing/ICD unit, wherein the readout unit/reader allows electromagnetic telecommunication and/or wireless powering of the sensor, the pacing/ICD unit at least interrogates the sensing device, and the external unit powers the device, in combination with all of the other limitations of the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735